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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,886

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/695,886	Applicant(s) LEDERMAN, ANDREW B.	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-12-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14 and 20-21, drawn to a suture needle, classified in class 606, subclass 228.
 - II. Claim 15-19, drawn to a method of using a suture needle, classified in class 606, subclass 228.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be performed with any suture needle, including a needle that does not necessarily contain a visual indicator.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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4. During a telephone conversation with Cynthia Lee on 7 August 2006 a provisional election was made without traverse to prosecute the invention of Invention I, claims 1-14 and 20-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

5. The disclosure is objected to because of the following: it is the examiner's position that applicant has invoked 35 U.S.C. 112, sixth paragraph in claim 11 and 12 by reciting "means for distinguishing." Therefore the examiner requires the applicant to clarify the record by amending the specification to "explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element." MPEP 2181(IV). Please note that the MPEP clearly states that "[e]ven if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...." (MPEP 2181(IV)). Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 recites the limitation "the curve" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-8, 11-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brunken (EP 0 615 726 A1).

11. Regarding Claims 1 and 10, Brunken'726 discloses a needle with a curved cylindrical shaft (2, Figure 1) being marked at least partially with a visual indicator (page 2, lines 29-34) and a puncture tip (6) at one end of the curve (see Figure 1) of the shaft (2).

12. Regarding Claim 2-7, Brunken'726 discloses a shaft having a front surface (near tip 6) that includes a visual indicator of bare or untreated metal, which is a first color, and a rear surface that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

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13. Regarding Claim 8, Brunken'726 discloses that the entire front surface of the needle consists of bare or untreated metal (first color) and rear surface can be continuously matte-finished or colored (second color) (page 2, lines 29-34 and Figure 1).

14. Regarding Claim 11, 12, and 14, Bunken'726 discloses a surgical needle with a curved cylindrical shaft (Figure 1) containing a puncture tip (6) and a shaft (2) extending from the tip (6) including a means for distinguishing between the front surface of the shaft (2) that is proximal to tip (6) and the rear surface of the shaft (2) that is distal to tip (6) (see Figure 1).

15. Regarding Claim 12, Brunken'726 discloses a shaft having a front surface (near tip 6) that includes a visual indicator of bare or untreated metal, which is a first color, and a rear surface that includes a visual indicator that is matte-finished or colored, which is a second color (page 2, lines 29-34).

16. Regarding Claim 13, Brunken'726 discloses that the entire front surface of the needle consists of bare or untreated metal (first color) and rear surface can be continuously matte-finished or colored (second color) (page 2, lines 29-34 and Figure 1).

17. Regarding Claim 20, Brunken'726 discloses a method of making a suture needle that includes providing a suture needle (page 3, lines 5-9) and marking at least a portion of the needle with a visual indicator (page 3, lines 14-17).

18. Regarding Claim 21, Brunken'726 discloses that the front surface is a different color than the rear surface of the needle (page 3, lines 18-19).

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Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brunken'726, as applied to Claim 1, in view of Anis (US Patent 5,352,233).

22. Brunken'726 teaches the limitations of Claim 9, except a mechanism for determining the needle's angle of orientation.

23. Anis'233 teaches a medical device in which a visual indicator on the device aids in determining the angle of orientation of the instrument (column 3, lines 58-68) in order to aid the surgeon in orienting the device (column 3, lines 30-36). Therefore it would have been obvious to one skilled in the art at the time the invention was made to use a visual indicator to aid in determining the angle of orientation of the device.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lmb



**MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER**